

## **CERTIFICATE OF ANALYSIS**

## DRAXIMAGE MAA MACROSALB (10 vials/kit)

2.5 mg of Stannous Albumin Macro Aggregate / vial

# Certificate:	2022MR07-1			
Batch Number:	1K139	Manufacturing Date:	2022JA17	
Lot Number (FP):	1K139A	Expiry Date:	01/2024	
Product Number:	3000001020	Specification Number and Version:	30000001020_v01	
Standard of Testing:	House, USP <sup>1</sup>	Date of Release: (Date with QA Initials)	2022 MRO7 MB	

		Tests on the Lyophilized product	
Test Description	Analytical Method	<u>Specifications</u>	Results
Description	10019	A white freeze-dried plug or powder, clean and free of foreign matter. The flip-off cap is blue.	Conforms
Resuspendability	10079	A white suspension which may separate on standing.	Conforms
рН	10005	5.2 – 6.0	5.5
Loss on Drying	10021	≤ 5%	2%
Particle Density	10088	3 - 8 x 10 <sup>6</sup> aggregated albumin particles in each vial	5x10E6 part./vial
	10080	Particle Size < 10 μm: ≤ 10%	8%
		Particle Size ≥ 10 μm - ≤ 70 μm: ≥ 90%	92%
Particle Size		Particle Size > 100 µm: ≤ 0.2%	< 0.1%
		Particle Size > 150 µm: none	None
MAA Identification	10000	A blue color develops.	Conforms
SnCl <sub>2</sub> .2H <sub>2</sub> O Assay	10039	≥ 0.06 mg/vial	0.11 mg/vial
Total Tin Assay	10040	≤ 0.12 mg	0.09 mg/vial
Stannous Albumin Macro Aggregated Complex	10082	2.2 – 3.0 mg/vial	2.5 mg/vial
Human Serum Albumin	10068	3.5 – 6.5 mg/vial (or alternative method 10089)	5.4 mg/vial
Sodium Chloride	10084	0.96 - 1.44 mg/vial	1.34 mg/vial
Residual Solvents <sup>1</sup>	USP<467>	Meets USP requirements (No test required)	Conforms
Sterility <sup>1,2</sup>	10007	Sterile	Conforms
Bacterial Endotoxins	10008	≤ 16.5 EU/vial	8.2 EU/vial

<sup>&</sup>lt;sup>2</sup>Outside testing

@ PR 14/021 MT2022 MROJ.

### A Jubilant Pharma Company



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Tests on the Reconstituted product				
Test Description	Analytical Method	Specifications	Results	
Radiochemical Purity	10043	Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at 15 – 30 minutes post labeling.		
		Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at least 12 hours post labeling.	100%	
Centrifugation Procedure	10087	Not more than 10% of the total radioactivity is found in the supernatant liquid, at 15 – 30 minutes post labeling.	3%	
		Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 12 hours post labeling.	2%	
Biological Distribution	10044	In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not less than 80% of the radioactivity is found in the lungs of the animal at 15 minutes post injection.		
		In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than a total of 5% of the radioactivity is found in the liver of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%	
		In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%	
		In not less than 2 of 3 animals, at 12 -24 hours post la less than 80% of the radioactivity is found in the lungs at 15 minutes post injection.		1: 99% 2: 93% 3: 98%
		In not less than 2 of 3 animals, at 12 - 24 hours post labeling, not more than a total of 5% of the radioactivity is found in the liver of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%	
		In not less than 2 of 3 animals, at 12 – 24 hours post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%	

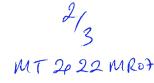
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This batch of product has been tested by Jubilant DraxImage Quality Control Laboratory under Canadian Establishment License Number **101869-A** and complies with the specification requirements.

MUSTAPHA TOLLABI

QC Sr. Supervisor

Verified by: Name and Title

Signature

M. Blale.

Date

2022 MR 07

NATHALIE BRUNET

QA, ASSOCIATE

Approved by: Name and Title Mathalie Bunet

Signature

2022HR07

Date

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